GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:2277
ANSWERED ON:15.12.2004
NATIONAL PHARMACO VIGILANCE COMMITTEE
Paraste Shri Dalpat Singh

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether a National Pharmaco Vigilance Committee has been formed ;

(b) if so, the composition of the Committee ;

(c) the terms of reference of this Committee ;

(d) whether the Committee has made any study on any of the recent issues; and

(e) if so, the details of its report, its recommendations and the action taken by the Government thereon?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a): Yes, Sir.

(b): The committee consists of following members in addition to the chairperson.

1. Chairperson Director General of Health Services

2. Member Secretary Drug Controller General (I)

3. Members:

1. Dr. N.K. Ganguly,
Director General,
Indian Council of Medical Research (ICMR)
Ansari Nagar, New Delhi-110 029.

2. Shri Rajesh Bhushan
Director Incharge (Drug Division)
Ministry of Health and Family Welfare,
Nirman Bhawan, New Delhi

3. Head, Department of Pharmacology,
AIIMS, New Delhi-29.

4. Dr. Nilima Kshirsagar
Dean, MS Building, 1st Floor,
Seth GS Medical College & KEM
Hospital, Parel, Mumbai-400 012.

5. Prof. Ranjit Roy Choudhary,
Emeritus Scientist and President of Delhi Society
for Promotion of Rational Use of Drugs,
National Institute of Immunology,
Aruna Asaf Ali Marg, New Delhi-110 067.

6. Dr. C. Adithan
Prof. Dept. of Pharmacology
JIPMER, Pondicherry-605 006

7. Dr. TD Dogra, Prof. and Head
Dept. of Forensic Medicine & Toxicology
All India Institute of Medical Sciences,
Ansari Nagar, New Delhi-110 029.

8. Prof. Anoop Mishra, Professor
Dept. of Medicine
All India Institute of Medical Sciences, PO Box # 4938,
Ansari Nagar, New Delhi-110 029.

9. Dr. A.K. Agarwal,
Consultant, Medicine
Ram Manohar Lohia (RML) Hospital
New Delhi.

10. Prof. SD Seth
Chair in Clinical Pharmacology
ICMR, Ansari Nagar, New Delhi-110 029.

11. Sh. Brijesh Regal
Apothecaries Ltd.
579. Devli, East Sainik Farms
New Delhi-110 062.

12. Prof. YK Gupta, Director
Industrial Toxicology Research Centre (ITRC),
PO BOX No.80, MG Marg,
Lucknow-226001, India.

13. Dr. MD Gupte, Director,
National Institute of Epidemiology,
ICMR, P.O. Box No.2577,
Mayor VR Ramanathan Road, Chetpet,
Chennai-600031.

14. Dr. Kusum Verma, Professor & Head
Dept. of Pathology
All India Institute of Medical Sciences,
Ansari Nangar, New Delhi-110 029.

15. Dr. Pramil Tiwari
Asso. Prof. & Incharge
Dept. of Pharmacy Practice
National Institute of Pharmaceutical Education & Research (NIPER)
Sector 67, SAS Nagar, Distt. Ropar
Punjab-160062, India

16. Dr. Urmila Thatte
Prof. & Head, Dept. of Clinical Pharmacology
BL Nair Hospital & Medical College,
Mumbai Central-400008.

(c): The mandate of National Pharmaco Vigilance Committee is to facilitate the National Pharmaco Vigilance Programme which has the following specific aims:-

1. Contribute to the regulatory assessment of benefit, harms, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost effective) use.

2. Improve patient care and safety in relation to use of medicines and all medical and paramedical interventions.

3. Improve public health and safety in relation to use of medicines.

4. Promote understanding, education and clinical training in Pharmaco vigilance and its effective communication to the public.

(d)&(e): Yes, Sir. The committee met on 11/10/04. The committee studied and deliberated upon the worldwide withdrawal of the drug Rofecoxib by M/s. Merck, USA and recommended to withdraw Rofecoxib from India. Notification in this respect is under publication.